

## Percutaneous Coronary Excimer Laser-Assisted Balloon Angioplasty: Initial Clinical and Quantitative Angiographic Results in 50 Patients

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The initial clinical experience and quantitative angiographic results of percutaneous coronary excimer laser-assisted balloon angioplasty are described for 55 lesions in 50 patients. With use of a xenon chloride (308 nm) excimer laser generator and 1.5 to 1.75 mm catheters, excimer laser angioplasty was attempted at 135 ns pulse width, 25 to 40 Hz repetition rate, 2 to 5 s laser delivery time and 30 to 60 mJ/mm<sup>2</sup> energy fluence. Laser success (>20% reduction in absolute percent diameter stenosis) was achieved in 41 (75%) of 55 lesions, with 100% subsequent balloon angioplasty success (<50% residual stenosis).

By quantitative digital caliper technique, the percent diameter stenosis (mean  $\pm$  SE) was reduced from  $81 \pm 1\%$  to  $54 \pm 3\%$  after excimer laser angioplasty ( $p < 0.001$ ) and to  $20 \pm 1\%$  after balloon angioplasty ( $p < 0.001$ ); minimal luminal diameter increased from  $0.56 \pm 0.04$  to  $1.46 \pm 0.06$  mm ( $p < 0.001$ ) and  $2.03 \pm 0.07$  mm ( $p < 0.001$ ), respectively. By videodensitometric techniques, the percent area stenosis decreased from  $86 \pm 2\%$  to  $54 \pm 3\%$  after excimer laser angioplasty ( $p < 0.001$ ) and to  $26 \pm 3\%$  after balloon angioplasty ( $p < 0.001$ ).

There were no perforations, need for emergency bypass surgery or deaths. The overall incidence of abrupt closure (3.6%), dissection (1.8%), embolization (1.8%), filling defect (6%), myocardial infarction (5.5%), side branch occlusion (3.6%) or spasm (3.6%) was infrequent and more related to subsequent balloon angioplasty than to the laser procedure. In the early follow-up period (range 1 to 10 months, mean 7), 36 (72%) of the 50 patients remained asymptomatic; symptoms recurred in 14 patients (28%) in relation to abrupt closure in the first 24 h in 2 patients (3.6%), late closure in the first week in 2 patients (3.6%) and restenosis in 10 patients (20%).

Thus, percutaneous coronary excimer laser angioplasty appears to be a feasible and safe procedure in selected patients. At present, the procedure is undergoing significant development, including modification of the delivery catheters and operating techniques. The impact of this technology on the angioplasty restenosis rate awaits further follow-up analysis.

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Initial attempts to perform percutaneous coronary laser angioplasty with a continuous wave argon laser-heated metal probe were complicated by difficulty in maneuvering the device in tortuous coronary arteries (1) and a high incidence of thermally induced thrombosis (2). Preliminary case reports and small clinical series (3-7) suggest that pulsed excimer laser angioplasty may be more feasible as a percutaneous coronary procedure; however, the safety and efficacy of this technique in a large series of patients have not been examined in detail. In this initial feasibility study, the clinical experience and quantitative angiographic results of our first 50 cases of percutaneous excimer laser-assisted

balloon angioplasty in native coronary arteries and saphenous vein bypass grafts are presented.

### Methods

**Study patients (Table 1).** Between May 8, 1989 and January 5, 1990, percutaneous coronary excimer laser angioplasty was attempted in 50 patients with 55 coronary artery stenoses after informed consent was obtained under a protocol approved by the Food and Drug Administration and the Institutional Review Board at Mount Sinai Medical Center. All patients had symptomatic coronary artery disease and one or more stenotic lesions of  $\geq 60\%$  that were amenable to conventional balloon angioplasty. Patients undergoing emergency angioplasty for acute myocardial infarction and the majority of patients undergoing multivessel angioplasty were excluded from the study. Patients with unstable angina and chest pain within 24 h were enrolled in a separate protocol evaluating the combination of urokinase and balloon angioplasty. Because of the prototypic nature of the early clinical devices, laser attempts were initially restricted to straight, proximal portions of the left and right

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**Table 1. Clinical and Angiographic Findings in 50 Patients**

<b>Clinical finding</b>	
Age (yr)	
Mean	57
Range	32 to 76
Gender	
Male	42 (84%)
Female	8 (16%)
Angina	
Stable	25 (50%)
Unstable	25 (50%)
Functional class (CCS)	
I	2 (4%)
II	5 (10%)
III	18 (36%)
IV	25 (50%)
<b>Angiographic finding (55 stenoses)</b>	
<b>Vessel treated</b>	
LAD	35 (64%)
LCx	11 (20%)
RCA	7 (13%)
SVG	2 (3%)
Repeat angioplasty	10 (18%)
Multivessel angioplasty	4 (7%)
Severity (%) of stenosis before (treatment lumen = SE)	81 ± 6*

CCS = Canadian Cardiovascular Society; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery; SVG = saphenous vein graft.

coronary arteries; however, with improvement in device flexibility and profile laser treatment of more distal lesions was attempted. Nevertheless, the cases comprised a highly selected study group representing only 20% of the total number of balloon angioplasty procedures performed in this period.

**Laser equipment.** A xenon chloride (308 nm) excimer laser generator (CVX-300, Spectranetics Corporation) delivered laser pulses of 135 ns pulse width at a frequency of 25 to 40 Hz and an energy fluence of 30 to 60 mJ/mm<sup>2</sup>. This laser generator has an automatic self-calibration system for precalibration of each catheter to deliver an energy fluence of 30 to 60 mJ/mm<sup>2</sup>. Once calibrated, the fluence could then be quickly adjusted to the desired fluence without the need to remove the catheter from the coronary artery for additional calibration. In the first 25 patients, the fiberoptic catheter had a 1.75 mm outer diameter and consisted of thirteen 200 µm fiber optics arranged concentrically around a central lumen for passage over a 0.014 to 0.018 in. (0.036 to 0.046 cm) guidewire (4). This catheter had a fiber/catheter tip area ratio of 0.195 with the luminal area of the guide wire subtracted. In the second half of the series, more flexible 1.5 and 1.75 mm central lumen catheters were used, which consisted of 20 and 40 concentrically arranged 100 µm fiber optics, respectively. These catheters had a fiber/catheter tip area (minus guidewire lumen) ratio of 0.150 and 0.105, respectively.

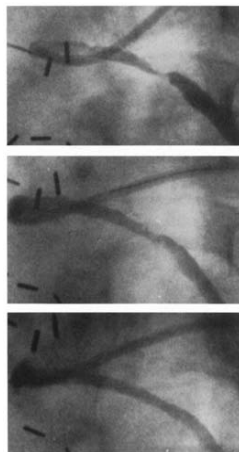
**Angioplasty protocol.** All patients were prepared for the procedure with use of standard angioplasty technique by the percutaneous femoral approach. Pretreatment medication consisted of oral aspirin (325 mg) and a calcium channel antagonist administered the night before and the day of the procedure. Conventional 8F guiding catheters were used in all but two cases in which a 9F guiding catheter was used. A standard angioplasty regimen of heparin (10,000 U intravenous bolus injection) and intracoronary nitroglycerin (100 µg) was given before baseline quantitative coronary cineangiography was performed.

**Angioplasty procedure.** First, a 0.014 to 0.018 in. (0.036 to 0.096 cm) guidewire was advanced separately across the lesion into the distal coronary artery, with its position confirmed fluoroscopically. After extending the guidewire, a laser catheter was then advanced over the guidewire up to the lesion. Small contrast injections of contrast medium (3 ml) confirmed the position of the laser catheter in direct contact with the origin of the lesion. Next, an attempt was made to advance the excimer laser catheter slowly through the lesion using a short 2 to 5 s laser delivery time and an initial energy fluence of 30 to 40 mJ/mm<sup>2</sup>. If a lesion was crossed on the first laser attempt, the catheter was withdrawn proximal to the lesion and angiography performed to confirm the result. As experience was gained, a combination of angiography and tactile feedback was used to decide whether additional passes through the lesion were necessary. Once a catheter passed smoothly through the site of the lesion, no further passes were attempted. If a lesion could not be traversed with the first 2 to 5 s laser attempt, additional attempts were made with a stepwise increase in energy fluence in increments of 10 mJ/mm<sup>2</sup> to a maximum of 60 mJ/mm<sup>2</sup>. After excimer laser angioplasty, repeat quantitative coronary arteriography was performed to document the result.

**Subsequent balloon angioplasty** was then performed in all but one patient to maximally reduce the luminal stenosis. After overnight heparinization, all sheaths were removed the next morning. Discharge medications included aspirin (325 mg/day) and other cardiac agents prescribed by the referring physician.

**Quantitative coronary arteriography.** Quantitative analysis of coronary stenoses was performed before and after laser angioplasty as well as after balloon angioplasty by using images acquired with a Fisher Imaging DF-100 digital subtraction angiographic unit coupled to a Phillips Cardiographic 100 X-ray generator as previously described (8). Coronary stenoses were quantified independently by both the digital caliper and videodensitometric methods (8). The differences in percent diameter stenosis, minimal luminal diameter and percent area stenosis were compared by using a paired Student's *t* test.

**Definitions.** Excimer laser angioplasty success was defined as passage of the laser catheter through the stenosis and >20% absolute reduction in the previous percent diam-



**Figure 1.** Angiograms of a combined excimer laser and balloon angioplasty of a stenosis in an 8 year old saphenous vein bypass graft to an obtuse marginal artery. **Top.** Initial 88% stenosis in the body of the saphenous vein bypass. **Middle.** Residual 26% stenosis after two passes of a 1.75 mm excimer laser catheter through the lesion at 40 mJ/mm<sup>2</sup> energy fluence, 25 Hz repetition rate and 74 and 72 pulses, respectively, for laser delivery times of approximately 3 s each. **Bottom.** Final 12% stenosis after subsequent dilation with a 3.5 mm balloon catheter.

eter stenosis. Balloon angioplasty success was defined as  $\leq 50\%$  residual stenosis.

## Results

**Acute angiographic results.** As assessed on the basis of intention to treat, the excimer laser catheter was able to traverse the lesion and reduce the percent diameter stenosis by  $\geq 20\%$  in 41 (75%) of the 55 coronary artery stenoses. The mean number of laser pulses per patient was 341 and the mean laser time per patient was 11.4 s. Because the average number of attempted laser passes per patient was four, the mean laser delivery time per attempt was 2.9 s. Figure 1 is a representative angiographic example of excimer laser angioplasty with subsequent balloon angioplasty of a stenosis in an 8 year old saphenous vein bypass graft.

**Laser energy fluence.** The major factors affecting laser success in this initial series were laser energy fluence, catheter flexibility and tip profile. With use of an energy fluence of 30 mJ/mm<sup>2</sup> and the original rather stiff catheter made up of thirteen 200  $\mu$ m fiber optics, excimer laser

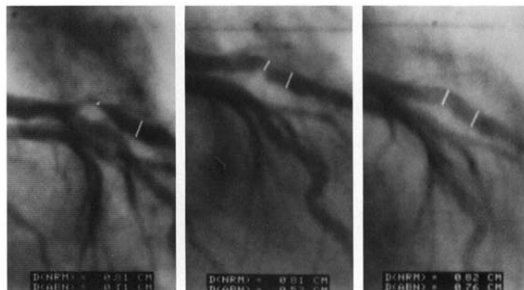
success was achieved in only four (50%) of the first eight patients. However, it was observed that an increase in energy fluence by as little as 10 mJ/mm<sup>2</sup> could result in laser success when the initial fluence (30 mJ/mm<sup>2</sup>) was unsuccessful. In later cases, a protocol was developed in which the starting energy fluence was 40 to 50 mJ/mm<sup>2</sup> and this level was increased up to a maximum of 60 mJ/mm<sup>2</sup> to attempt laser recanalization. Using this protocol, 8 (62%) of 13 excimer laser attempts could be converted from an initial laser failure to a laser success by simply increasing the laser fluence while the catheter was still in the coronary artery.

**Device limitations.** Catheter flexibility and tip profile also limited excimer laser success in this initial series. In three patients, vessel tortuosity and poor guide support contributed to what was considered to be unsafe advancement of the device to the lesion; no laser energy was delivered and conventional balloon angioplasty was performed. These patients were excluded from quantitative angiographic analysis because excimer laser angioplasty was not attempted; however, these patients were included in the overall analysis of clinical success and complications as the laser catheter was advanced into the coronary artery. Use of more flexible catheters with 100  $\mu$ m fiber optics improved the ability to treat lesions in more tortuous coronary arteries. Furthermore, on at least one occasion, a smaller 1.5 mm catheter was able to traverse a lesion that could not be crossed with a 1.75 mm device at the same laser fluence.

**Quantitative digital arteriographic analysis (Fig. 2).** By digital quantitative arteriographic analysis of the coronary stenosis, the mean percent diameter stenosis (mean  $\pm$  SE) was significantly reduced from  $81 \pm 1\%$  to  $50 \pm 3\%$  after excimer laser angioplasty ( $p < 0.001$ ) and to  $20 \pm 1\%$  after subsequent balloon angioplasty ( $p < 0.001$ ). The minimal luminal diameter increased from  $0.56 \pm 0.04$  mm to  $1.46 \pm 0.08$  mm after excimer laser angioplasty ( $p < 0.001$ ) and to  $2.30 \pm 0.07$  mm after balloon angioplasty ( $p < 0.001$ ). By digital videodensitometric analysis, the mean percent area stenosis decreased from  $86 \pm 2\%$  to  $54 \pm 3\%$  after excimer laser angioplasty ( $p < 0.001$ ) and to  $26 \pm 3\%$  after balloon angioplasty ( $p < 0.001$ ) (Fig. 3). In the 39 lesions in which the 1.75 mm excimer laser catheter was successful, the mean minimal luminal diameter increased from  $0.54 \pm 0.004$  mm to  $1.71 \pm 0.08$  mm. In two lesions in which the 1.5 mm excimer laser catheter was successful, the mean minimal luminal diameter increased from  $0.80 \pm 0.04$  mm to  $1.39 \pm 0.09$  mm.

**Complications (Table 2).** With use of an over the wire system, excimer laser angioplasty could be performed with an impressively small number of complications. Specifically, there was no laser-related abrupt closure, dissection, embolization, perforation or side branch occlusion. There were one laser-related filling defect and one laser-related episode of vessel spasm without angina; the first was successfully treated with balloon angioplasty and the second with intracoronary nitroglycerin and balloon dilation. There were no major complications such as death, myocardial infarction or the need for emergency bypass surgery attributed to the

**Figure 2.** Right, Digital quantitative arteriographic analysis of an 82% eccentric mid left anterior descending artery stenosis. Middle, Stenosis reduced to 42% by three passes of a 1.75 mm excimer laser catheter through the lesion at 43 mJ/mm<sup>2</sup> energy fluence, 25 Hz repetition rate and 160, 89 and 47 pulses for laser delivery times approximately 6, 3 and 2 s, respectively. With each attempt, the passage of the excimer laser catheter through the stenosis was met with less resistance. Left, There is a 14% residual stenosis after dilation with a 2.5 mm balloon catheter.



excimer laser procedure. No patient experienced any angina, electrocardiographic changes, bradycardia or arrhythmias during the laser procedure or while the laser catheter was in the coronary artery.

Although it is difficult to attribute complications to either the laser or the balloon catheter when they are used sequentially, there were also only a small number of complications after balloon angioplasty (Table 2). Of the two abrupt closures, one occurred in the laboratory and was related to a spiral dissection after balloon angioplasty of a residual stenosis that was not dissected after excimer laser angioplasty. The other abrupt closure appeared 24 h after the procedure and was attributed to 9F guiding catheter trauma to the ostium of a right coronary artery. Excimer laser angioplasty was unsuccessful in this case and conventional balloon angioplasty was performed. There were no deaths or need for emergency bypass surgery. Non-Q wave myocardial infarction occurred in three patients (6%) as a result of balloon angioplasty-related side branch occlusion in two and distal embolization in one patient.

**Clinical follow-up.** In the early clinical follow-up period of 1 to 10 months (mean 7), patients treated with coronary excimer laser angioplasty have not demonstrated any increase in clinical recurrence of symptoms; however, the follow-up duration has been short. To date, 39 (78%) of the 50 patients remain asymptomatic; symptoms of angina have recurred in a total of 14 patients (28%) in relation to abrupt closure confirmed by angiography in the first 24 h in 2 patients (3.6%), late closure confirmed angiographically in the 1st week in 2 patients (3.6%) and restenosis confirmed by angiography in 10 patients (20%). Six of the 10 cases of restenosis occurred in patients treated early in the series in which excimer laser angioplasty was unsuccessful.

## Discussion

**Initial results with prototype catheters.** In the first 50 patients at Mount Sinai Medical Center in which this partic-

ular excimer laser angioplasty system was used, laser success was achieved in 36 (72%) of 50 patients and 41 (78%) of 55 lesions, whereas more flexible lower profile balloon catheters were ultimately successful in 100% of patients. Laser failure was due to inability to completely cross a lesion and was attributed to the following causes: inability to come in contact with the lesion, no energy delivered ( $n = 3$ ); low energy fluence ( $n = 4$ ); large device profile, catheter "dead space" or calcified lesion ( $n = 7$ ). There are insufficient data to compare results in calcified versus noncalcified lesions. These results for excimer laser angioplasty are similar to those reported in small series of patients (5-7) in whom two other excimer (308 nm) laser delivery systems (Advanced Interventional Systems; Technolas) were used. Limited catheter flexibility and poor tip profile were characteristic of all these early devices; however, improvements in the delivery systems are consistently being made. Alternative size catheters already exist in both larger (2 mm) and smaller (1.5 mm) diameters.

As has already been observed with the 1.5 mm catheter, smaller devices may be required to initiate laser recanalization for further follow-up treatment with a larger device. Conversely,  $\geq 2$  mm devices may offer the potential advantage of excimer laser angioplasty alone without subsequent balloon angioplasty (9).

**Evolving laser variables.** Several excimer laser variables were also modified during this series. Excimer laser fluence was increased from 30 to a maximum of 60 mJ/mm<sup>2</sup> during this investigation and in eight patients, an increase in the laser fluence using the automatic calibration system provided a successful result when the lesion could not be crossed at a lower fluence. Higher laser fluence is technically possible and may be required in the future; however, the safety of using a fluence  $>60$  mJ/mm<sup>2</sup> with this particular delivery system has not been assessed in the experimental laboratory. In several early cases, the repetition rate was increased from 25 to 40 Hz in an attempt to improve the ablation rate; however, this was not found to be as

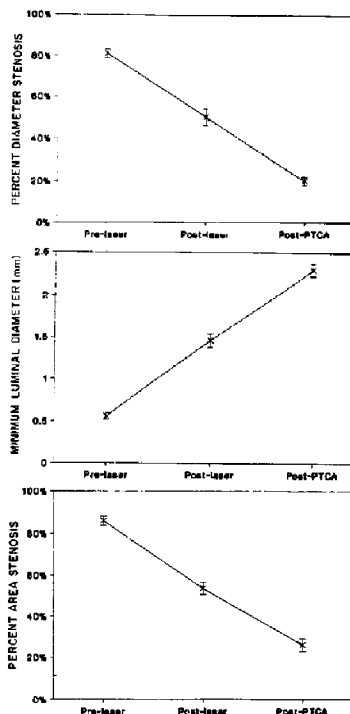


Figure 3. Digital quantitative arteriographic analysis of percent diameter stenosis (top), minimal luminal diameter (mm) (middle) and percent area stenosis (bottom) before (Pre) and after (Post) angioplasty and balloon angioplasty (PTCA). Data are mean values  $\pm$  SE.

successful as increasing the laser fluence. With this particular laser generator, the pulse duration was kept constant at 135 ns during the entire study. Insufficient data have been published (3,7) about the other two excimer laser systems to draw any conclusions on the ideal laser variables. These studies (5,7) report the use of repetition rates of 20 Hz, pulse durations of 60 and 85 ns and energy fluences in the range of 35 to 40 mJ/mm<sup>2</sup>; however, higher energy fluence up to 50 mJ/mm<sup>2</sup> have recently been used with at least one of these systems (9). Additional clinical investiga-

Table 2. Procedural Complications

	Guiding Catheter-Related No. (%)	Laser-Related No. (%)	Balloon-Related No. (%)	Total No. (%)
By lesion (n = 55)				
Abrupt closure (< 24 h)	1 (1.8)	0	1 (1.8)	2 (3.6)
Dissection	0	0	1 (1.8)	1 (1.8)
Embolization	0	0	1 (1.8)	1 (1.8)
Filling defect	0	1 (1.8)	2 (3.6)	3 (5.5)
Perforation	0	0	0	0
Side branch occlusion	0	0	2 (3.6)	2 (3.6)
Spasm	1 (1.8)	1 (1.8)	0	2 (3.6)
By patient (n = 50)				
Emergency CABG	0	0	0	0
Death	0	0	0	0
MI (CK > 200 U)	0	0	3 (6.0)	3 (6.0)

CABG = coronary artery bypass grafting; CK = creatine kinase; MI = myocardial infarction.

tion will be necessary to determine the optimal excimer laser variables.

**Laser angioplasty techniques: potential relation of coronary vasospasm to long laser delivery time.** The present study was remarkable for a low incidence of laser- or procedure-related complications. These observations have been confirmed with one other coronary excimer laser system (3,6); however, with a third system, preliminary reports (5,7) indicate a higher incidence of complications (vasospasm, intraluminal filling defects and abrupt closure); in particular, coronary vasospasm was observed in 20% to 53% of patients. From these brief reports, it is difficult to determine which procedural factors are responsible for this discrepancy; however, the long laser delivery time of 10 to 30 s per laser attempt (7) may be one important factor. In the present study, a shorter laser delivery time of 2 to 5 s per attempt (mean 2.9 s) and a brief interval >1 min between attempts were used; these procedures evolved as a result of experimental and clinical investigations (1,10,11) of several coronary laser systems including the laser probe, the laser balloon catheter and the excimer laser catheter. The one episode of excimer laser-related coronary vasospasm in this series occurred after a 4 s laser delivery time in a bend of a distal left circumflex coronary artery; thus, mechanical trauma could also explain this event.

In contrast to the practice of obstructing coronary blood flow during a balloon angioplasty procedure, the lack of ischemic events (angina, electrocardiographic changes or arrhythmias) during excimer laser angioplasty is probably related to the fact that the laser catheter never obstructed flow for more than a few seconds.

**Optimal number of laser passes.** An additional aspect of laser treatment that requires further investigation is the optimal number of passes that should be made through the lesion. Initially, the excimer laser angioplasty procedure was considered complete after the lesion was traversed a single

time. Later, it was found that repeat passes through a lesion provided smoother passage with each subsequent attempt as well as a greater reduction in the percent diameter stenosis. Thus, tactile feedback to the operator as well as angiographic appearance entered into the decision of when to continue or conclude the excimer laser angioplasty procedure. Additional factors such as the pressure gradient across the lesion or the ultrasonic or angiographic appearance of the lesion may aid in assessing the result of excimer laser angioplasty. This additional information may help determine when to stop the excimer laser procedure to prevent vascular trauma of dissection or perforation. At present with angiographic analysis alone, it is impossible to determine to what extent luminal improvement is due to true laser vaporization versus a mechanical (that is, Dotter) effect. Perhaps intraluminal ultrasonography will help answer this issue.

**Follow-up results.** Our preliminary clinical follow-up results are encouraging; however, the observation time is short. The majority of patients are just now returning for 6 month follow-up angiography. The clinical follow-up data of these patients are currently the subject of a multicenter registry (12). The effects of various procedural factors such as the size of the fiber-optic device and the residual stenosis after excimer laser angioplasty will be examined.

**Conclusions.** Percutaneous coronary excimer laser angioplasty appears to be a feasible and safe procedure in a highly selected group of patients; however, the fiber-optic catheters, laser-operating variables and angioplasty techniques are all undergoing significant development and modification. Once the equipment and techniques have become more established, randomized trials should be initiated to compare excimer laser angioplasty or excimer laser-assisted balloon angioplasty with conventional balloon angioplasty to determine whether this technology improves angioplasty safety or restenosis rates. However, on the basis of present results,

randomized clinical trials are not worth considering until a larger channel can be created by laser vaporization to result in greater reduction in the stenosis to <50%.

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